

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Roger Goldberg, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Plaintiffs' Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 4829]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **GRANTED in part, DENIED in part, and RESERVED in part.**

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis.

To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Goldberg is the Director of the Division of Urogynecology at NorthShore University HealthSystem and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. He is a member of the board of directors for the American Urogynecologic Society and is the co-inventor of the Uphold.

1. Conflict of Interest

First, the plaintiffs argue that Dr. Goldberg is biased in favor of the Uphold because he invented it and because he testified that he has been paid approximately \$1.4 million from BSC since 2005. I find such an argument unavailing under *Daubert*. Bias and witness credibility are appropriate topics for cross-examination. The plaintiffs' Motion with respect to this matter is **DENIED**.

2. Personal Experience

Second, the plaintiffs argue that Dr. Goldberg's opinions on the Uphold's safety should be excluded as unreliable because they are based solely on his personal experience. I disagree. *Daubert* permits an expert to rely heavily on his experience to form opinions. Even so, Dr. Goldberg's relied-upon list plainly reveals that he also considered scientific literature in forming his opinions. I decline to impose a blanket exclusion on all of Dr. Goldberg's safety opinions on the reasoning that they are based on his personal experience. The plaintiffs' Motion with respect to this matter is **DENIED**.

3. Complication Rate

Third, the plaintiffs argue that Dr. Goldberg's opinion that the complication rate for the Uphold is less than three percent should be excluded because it is based on a calculation of cases at his medical center and is not supported by any scientific studies. However, it does appear to be supported by scientific studies—specifically, Dr. Goldberg's data was published by a peer-reviewed journal. *See* Manhan K. Vu et al., *Minimal Mesh Repair for Apical and Anterior Prolapse: Initial Anatomical and*

Subjective Outcomes, 23 Int. Urogynecol. J. 1753, 1753–61 (2012). Accordingly, I find the plaintiffs’ challenges without merit, and the Motion as to complication rates is **DENIED**.

4. Physical Properties of Polypropylene

Fourth, the plaintiffs challenge Dr. Goldberg’s qualifications to opine on the physical properties of mesh because he is not a materials scientist, biomedical engineer, or a pathologist and admits as much. However, his extensive clinical experience surgically treating pelvic floor disorders with mesh, as well as his review of and contributions to the medical and scientific literature adequately qualify him to opine on polypropylene. Accordingly, the plaintiffs’ Motion as to Dr. Goldberg’s qualifications is **DENIED**.

Next, the plaintiffs challenge the reliability of Dr. Goldberg’s opinion on the physical properties of mesh—specifically that the device in question does not degrade, contract, or encapsulate. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court’s gatekeeping function requires more than simply “taking the expert’s word for it.”

Fed. R. Evid. 702 advisory committee’s note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (“We’ve been presented with only the expert’s qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that’s not enough.”)).

Yet the Fourth Circuit appears more willing to “take the expert’s word for it” so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App’x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer’s experience with “hundreds of cases of accidents” and “decades of experience in the industry in general” provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert’s testimony was nothing more than personal opinion because of his “years of experience” and assurance that all of his opinions were “to a reasonable degree of engineering certainty”).

On the one hand, Dr. Goldberg has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 (“[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”).

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Goldberg did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of

identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Goldberg reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Goldberg's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

5. Response to Plaintiff's Experts' Claims

Lastly, the plaintiffs argue that all of Dr. Goldberg's opinions in response to the plaintiff's experts' claims should be excluded because he is not qualified and his method was unreliable. Specifically, the plaintiffs object to Dr. Goldberg's opinions on (1) vaginal mesh implantation, (2) the Material Data Safety Sheet ("MSDS"), and (3) the severity of complications in the Directions for Use ("DFU").

a. Vaginal Mesh Implantation

The plaintiffs challenge the reliability of Dr. Goldberg's opinion that the plaintiffs' experts are wrong that bacteria in the vagina make transvaginal mesh surgery inadvisable—specifically that polypropylene does not become routinely infected. Dr. Goldberg claims he based this opinion on his clinical experience, during

which he did not encounter mesh infection, and upon peer-reviewed literature. This opinion presents the same challenges to assessing reliability as those discussed above. For the reasons discussed at length in my analysis of Dr. Goldberg's opinions on the physical properties of polypropylene, I am without sufficient information at this time to determine the reliability of his opinions on mesh infection. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

b. Material Safety Data Sheet ("MSDS")

The plaintiffs argue that Dr. Goldberg is unqualified to opine as to the MSDS for polypropylene mesh. Specifically, the plaintiffs seek to exclude Dr. Goldberg's opinions that he does not use the MSDS in making clinical decisions, and that the MSDS is not supported by scientific evidence. Dr. Goldberg's opinions on his and other doctors' experience with the MSDS for raw polypropylene pellets is not relevant or helpful to the jury. The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials BSC uses to manufacture its medical devices. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Goldberg's MSDS opinions for trial.

c. Adequacy of Warnings

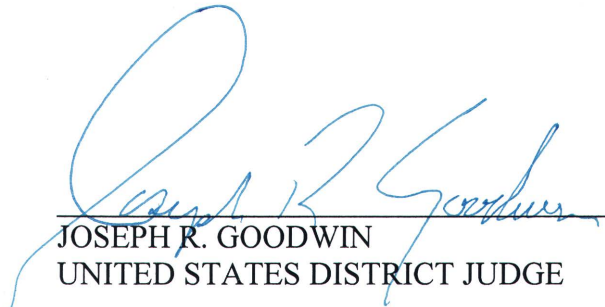
Dr. Goldberg does not provide the court with the basis of his opinion relating to the DFU, so the court cannot conclude it was the result of a reliable methodology. *See Daubert*, 509 U.S. at 590 (“Proposed testimony must be supported by appropriate validation”). Dr. Goldberg’s opinion is therefore **EXCLUDED** as unreliable. Accordingly, the plaintiffs’ Motion on this point is **GRANTED**.

IV. Conclusion

To summarize, the plaintiffs’ *Daubert* Motion concerning Dr. Goldberg [ECF No. 4829] is **GRANTED in part, DENIED in part, and RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-00049	Parker et al v. Boston Scientific Corporation
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-00304	Martinez v. Boston Scientific Corporation
2:17-cv-00307	Michael v. Boston Scientific Corporation
2:17-cv-00314	Newton v. Boston Scientific Corporation
2:17-cv-00315	Norris v. Boston Scientific Corporation
2:17-cv-00317	Norris v. Boston Scientific Corporation
2:17-cv-00318	Osborn v. Boston Scientific Corporation
2:17-cv-00325	Pick v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-00536	Sutiff v. Boston Scientific Corporation
2:17-cv-00568	Mahnke v. Boston Scientific Corporation
2:17-cv-00701	Babcock v. Boston Scientific Corporation
2:17-cv-01074	Dembski v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation

2:17-cv-01109	Herbert et al v. Boston Scientific Corporation
2:17-cv-01241	Tigner v. Boston Scientific Corporation
2:17-cv-01242	Evans v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-01837	Allen v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-01862	Faso et al v. Boston Scientific Corporation
2:17-cv-01900	Hauff et al v. Boston Scientific Corporation
2:17-cv-01925	Skalniak et al v. Boston Scientific Corporation
2:17-cv-01932	Peach v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-01939	Price v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation
2:17-cv-01977	Hardwick v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-01990	Hill-Sober et al v. Boston Scientific Corporation
2:17-cv-01996	Benson v. Boston Scientific Corporation

2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02106	Wilson v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation
2:17-cv-02110	Clark v. Boston Scientific Corporation
2:17-cv-02111	Busby v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-02243	Alvarado v. Boston Scientific Corporation
2:17-cv-02244	Speed v. Boston Scientific Corporation
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02417	Masterson v. Boston Scientific Corporation
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02446	Blalock v. Boston Scientific Corporation
2:17-cv-02447	Casale v. Boston Scientific Corporation
2:17-cv-02448	Clark v. Boston Scientific Corporation
2:17-cv-02449	Cole v. Boston Scientific Corporation
2:17-cv-02450	Wallace v. Boston Scientific Corporation
2:17-cv-02459	Mallory v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation

2:17-cv-02462	McSween v. Boston Scientific Corporation
2:17-cv-02467	Melrose v. Boston Scientific Corporation
2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02471	McFalls v. Boston Scientific Corporation
2:17-cv-02477	Pouncy v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02486	Daniell v. Boston Scientific Corporation
2:17-cv-02505	Cutlip v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-02524	Murphy v. Boston Scientific Corporation
2:17-cv-02525	Price v. Boston Scientific Corporation
2:17-cv-02527	Roark v. Boston Scientific Corporation
2:17-cv-02528	Saldivar v. Boston Scientific Corporation
2:17-cv-02531	Smith v. Boston Scientific Corporation
2:17-cv-02533	Southwood v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-02553	Spencer v. Boston Scientific Corporation

2:17-cv-02554	Stark v. Boston Scientific Corporation
2:17-cv-02562	Vincent v. Boston Scientific Corporation
2:17-cv-02566	Walker v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation
2:17-cv-02588	Adams v. Boston Scientific Corporation
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-02590	Childress v. Boston Scientific Corporation
2:17-cv-02592	Dickeson v. Boston Scientific Corporation
2:17-cv-02596	McFolling v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-02598	Reid v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02600	Rinaldi v. Boston Scientific Corporation
2:17-cv-02601	Woodard v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation
2:17-cv-02636	Walseth v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation

2:17-cv-02641	Harrison-Hood v. Boston Scientific Corporation
2:17-cv-02646	Gottfreid v. Boston Scientific Corporation
2:17-cv-02730	Black v. Boston Scientific Corporation
2:17-cv-02734	Henjum v. Boston Scientific Corporation
2:17-cv-02738	Martin v. Boston Scientific Corporation
2:17-cv-02739	Martinez v. Boston Scientific Corporation
2:17-cv-02742	Morales v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02787	Stapf v. Boston Scientific Corporation